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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/544,910	04/07/00	HUANG Y	06510/121US1

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EXAMINER	
NIKODEM,D	
ART UNIT	**PAPER NUMBER**
1633	4

DATE MAILED: 10/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)	
	09/544,910	HUANG ET AL.	
	Examiner	Art Unit	
	David Nikodem	1633	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *29 August 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a method of reducing VLDL and/or triglyceride plasma levels in a host, and a method of treatment of a disease condition associated with elevated VLDL and/or triglyceride levels, by administration of an effective agent, classified as unclassifiable since the agent was not identified.

II. Claims 12-33 drawn to transgenic animals and methods of using said animals to screen compounds, classified in class 800, subclasses 3, 9, 14 and 18.

III. Claims 34 and 35, drawn to therapeutic compounds and pharmaceutical compositions thereof, classified as unclassifiable since the therapeutic compounds have not been identified.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a method of

reducing VLDL levels in a subject can be achieved by using agents and/or drugs other than the agent of invention III.

3. Inventions II and III are patentably distinct from the other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and are wholly different products, with different modes of operation, function and/or effect. Transgenic animals and therapeutic compounds are distinct products, with distinct protocols, materials and reagents required to make and/or use each invention. Further, different scientific considerations are needed in order to make and/or use each invention. Transgenic animals require the consideration of genetic manipulation, whereas therapeutic compounds require the consideration of drug delivery, concentration effects, drug uptake and drug targeting. In view of such, the inventions are patentably distinct, each capable of supporting an individual patent.

4. Inventions I and II are patentably distinct, each from the other. Although the claims are all drawn to methods, Invention I is drawn to a method of reducing VLDL plasma levels, whereas Invention II is drawn to a method of screening for a therapeutic agent. The two inventions have methods directed towards separate and distinct uses, modes of operation and effect. The protocols, materials and reagents necessary to practice each method are wholly different. Invention I requires the consideration of identifying VLDL associated diseases, and drug delivery, uptake and efficacy considerations, whereas Invention II requires the consideration of screening and

identifying therapeutic agents, which are completely different in structure and function than genes. In view of the aforementioned scientific considerations, the inventions are separate products, with separate functions and modes of operations, and thus, capable of supporting individual patents.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-III require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. Claims 1-11, 34 and 35 are generic to a plurality of disclosed patentably distinct species comprising antibodies, peptides, saccharides, fatty acids, nucleic acids and derivatives thereof and anti-sense molecules. Although these species are not listed in the claims, the specification is drawn to agents of the aforementioned species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Nikodem whose telephone number is (703) 308-8361. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-8724 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

DEBORAH J.R. CLARK
PRIMARY EXAMINER

David Nikodem
October 5, 2000